DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

April 1, 1999

Our Reference Numbers: 96-1099

Dr. Ute Krahl
Centeon Pharma G.m.b.H.
P.O. Box 1230
D-35002 Marburg
GERMANY

Dear Dr. Krahl:

Enclosed please find U.S. License No.1202 issued in accordance with the provisions of Section 351(a) of the Public Health Service Act, as amended November 21, 1997 (Food and Drug Administration Modernization Act; Public Law 105-115). Centeon Pharma G.m.b.H., Marburg, Germany, is hereby authorized to introduce or deliver for introduction into interstate commerce Antihemophilic Factor/von Willebrand Factor Complex (Human) [Humate-P®] for which your company has demonstrated compliance with establishment and product standards. Therefore, in accordance with the provisions in Title 21 Code of Federal Regulations (CFR) Section 601.5(a) Establishment License No. 1202 and the Product License for Antihemophilic Factor (Human), are hereby revoked, effective this date.

Antihemophilic Factor/von Willebrand Factor Complex (Human) [Humate-P®] is indicated (1) in adult patients for treatment and prevention of bleeding in hemophilia A (classic hemophilia) and (2) in adult and pediatric patients for treatment of spontaneous and trauma-induced bleeding episodes in severe von Willebrand disease and in mild and moderate von Willebrand disease where use of desmopressin is known or suspected to be inadequate.

Under this license you are authorized to introduce or deliver for introduction into interstate commerce Antihemophilic Factor/von Willebrand Factor Complex (Human) [Humate-P®]. Changes to the product, production process, location of production process, equipment, facilities, or responsible personnel are required to be reported to FDA as specified in Title 21 CFR Section 601.12.

The dating period for this product shall be 24 months from the date of manufacture when stored at 2-8° C. Within this period Humate-P® may be stored at room temperature, not to exceed 30° C, for up to six months. The date of manufacture shall be defined as the date of first final sterile filtration. Results of ongoing stability studies should be submitted throughout the dating period as they become available.

You are requested to submit samples of each future lot of this product together with protocols showing results of all applicable tests. No lots of product shall be distributed until notification of release is received from the Director, Center for Biologics Evaluation and Research (CBER).

All adverse experience reports should be submitted according to 21 CFR 600.80 to the Center for Biologics Evaluation and Research, HFM-210, Food and Drug Administration, 1401 Rockville Pike, Rockville, Maryland 20852-1448. It is also requested that distribution reports be submitted according to 21 CFR 600.81.

Please submit three (3) copies of final printed labeling at the time of use accompanied by Part II of Form FDA 2567 with completed implementation information. You may wish to submit additional advertising and promotional campaign material. If so, please submit three (3) copies of the proposed material in draft form with Part I of the Form FDA 2567/2253 to CBER, Advertising and Promotional Labeling Staff (APLS), HFM-602, 1401 Rockville Pike, Rockville, Maryland 20852-1448. Promotional claims should be consistent with and not contrary to the approved labeling. No comparative claims or claims of superiority over other similar products should be made unless data to support such claims are submitted to and approved by the Center for Biologics Evaluation and Research. Final copies of advertising and promotional materials should be submitted at the time of use with Part II of Form FDA 2567/2253 to APLS. Please include copies of the approved labeling with your proposed or final copy of advertising and promotional materials submitted to CBER.

Please acknowledge receipt of the enclosed license to the Director, Division of Blood Applications, HFM-370, Center for Biologics Evaluation and Research, 1401 Rockville Pike, Rockville, Maryland 20852-1448. Establishment License No. 1202 and the Product License for Antihemophilic Factor (Human), dated August 22, 1996, should be forwarded to the Director, Division of Manufacturing and Product Quality, HFM-670. These licenses should be returned in order that notation of revocation may be made thereon, after which they will be returned to you for your files.

Sincerely yours,

for Jay S. Epstein, M.D.
Director
Office of Blood Research and Review
Center for Biologics
Evaluation and Research

Steven A. Masiello
Acting Director
Office of Compliance
and Biologics Quality
Center for Biologics
Evaluation and Research